REMARKS

Claims 1-14, 18-22, and 24-27 are currently pending in the present application. Claims 18 and 27 are amended herein. By this amendment, claims 1-14, 18-22, and 24-27 are pending.

Rejection of claims 18-22 and 24-27 under 35 U.S.C. §112, first paragraph

The Examiner rejects claims 18-22 and 24-27 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The office action asserts that while the specification is enabling for treating or preventing vascular disease, the specification is not enabling for treating or preventing dementia.

Applicant has amended claims 18 and 27 to delete dementia, thereby rendering moot the rejection. This amendment is made without prejudice to pursue treating or preventing dementia in a continuation application. Applicant respectfully requests withdrawal of the rejection of claims 18-22 and 24-27 under 35 U.S.C. §112, first paragraph.

Rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a)

The Examiner rejects claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 0 595 005 A1 (hereinafter the European Patent) in view of Shapira (U.S. Patent No. 5,993,866, hereinafter Shapira). Applicant respectfully traverses this rejection.

The Examiner asserts that the European patent teaches administration of a composition consisting of vitamin B12, vitamin B6, folic acid, with an antioxidant such as vitamin E, and that the vitamin B12 may be in the form of cyanocobalamin, hydroxycobalamin or both. The Examiner also asserts that Shapira discloses that magnesium is essential for the vitamin B6 function and cites column 6, lines 1-20 in this regard.

Applicant respectfully asserts that Shapira incorrectly describes at column 6, lines 2-5 the content of Fonda et al., (1995, Arch. Biochem. Biophys. 320(2):345-52). The remainder of lines 6-20 in Shapira discuss S adenosyl methionine (SAM) requirements for magnesium and are

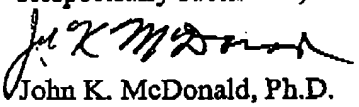
irrelevant. Fonda reports that magnesium affects erythrocytic pyridoxal phosphatases that catalyze hydrolysis of pyridoxal 5'-phosphate (PLP) (column 2, page 345 of Fonda (copy of Fonda attached as Exhibit A)). Erythrocyte pyridoxal phosphatases require magnesium for activity (column 2, 2nd paragraph page 345 of Fonda). Fonda does not disclose that magnesium is essential for vitamin B6 function, rather Fonda addresses the divalent cation requirements for the enzyme, erythrocyte pyridoxal phosphatase. For at least this reason, one of ordinary skill in the art would not interpret Fonda to state that magnesium is essential for Vitamin B6 function, but is required as a cofactor for erythrocytic pyridoxal phosphatase. Further, one of ordinary skill in the art would not be motivated, reading the Fonda article (as misinterpreted by Shapira), which involves divalent cations as cofactors for pyridoxal phosphatase, to combine this information with the European patent and derive Applicant's claimed vitamin composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E, and its use for treating or preventing vascular disease. Applicant's invention is not concerned with divalent cation requirements for the enzyme, erythrocyte pyridoxal phosphatase. Vitamin B6 as pyridoxal, pyridoxamine or pyridoxine (page 6 of the specification) is a component of Applicant's vitamin composition, not the enzyme pyridoxal phosphatase. Applicant's also assert that one of ordinary skill in the art would not combine the cited references, as Shapira misquotes Fonda which is an enzyme kinetics manuscript, with the European patent involving pharmaceutical preparations. Applicant asserts that one of ordinary skill in the art would not combine references from these distinctive fields and that the combination is improper.

The Examiner also asserts that Shapira teaches that hyperhomocysteinemia relates to cardiovascular disease, and that this would provide motivation to one of ordinary skill in the art to use Applicant's composition for the treatment and prevention of vascular disease. Applicant's traverse and respectfully assert that Shapira, which misquoted the content of Fonda, does not provide motivation to use Applicant's claimed composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E. Nothing in Shapira, alone or in combination with the European patent, provides motivation to derive Applicant's claimed composition (reasons discussed above), or to use Applicant's claimed composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E for the treatment and prevention of vascular disease.

For at least the reasons presented above, the cited art, alone or in combination, does not teach, suggest or provide motivation to derive the claimed composition consisting of vitamin B12, vitamin B6, folic acid, magnesium and vitamin E or its use in the recited method. Applicant respectfully requests withdrawal of the rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a).

Applicant respectfully asserts that this response to the office action is timely filed and that the rejections delineated in the office action of July 22, 2005 have been overcome. If any informalities remain which may be discussed, a conference with the undersigned is respectfully requested. Further, if minor amendments may be achieved by Examiner's amendment, a call to the undersigned attorney is also respectfully requested.

Respectfully submitted,



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